DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

PRODUCT LICENSE APPLICATION FOR THERAPEUTIC EXCHANGE PLASMA

Form Approved; OMB No. 0910-0124.
Expiration Date: November 31, 2001
See OMB Statement on Page 3.

DATE SUBMITTED

NOTE: This report is mandated by Section 351 of the Public Health Service Act; the Federal Food , Drug and Cosmetic Act, Section 502 and Title 21 CFR Part 600. No license may be granted unless this completed application form has been received.

INSTRUCTIONS

Type or print legibly in ink. Complete all items. Enter "NA" for items which are not applicable. If more space is needed for any item, continue on an 8-1/2 X 11 inch sheet, reference the entry by item number, and attach. Allow 1 inch top margin for filing purposes. Submit the original and one copy of the completed application. Assemble and staple each set, including all attachments. The application forms must be dated and signed by the Responsible Head. Return the application to DHHS/PHS, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM-370), 1401 Rockville Pike, Rockville, MD 20852-1448.

A separate product license application must be filed for each location of the establishment wishing to process, store and sell Therapeutic Exchange Plasma. Additional copies of the Standard Operating Procedures Manual need not accompany the license application provided and approved SOP Manual is on file with the Center for Biologics Evaluation and Research or has been submitted and all procedures being performed at the locations seeking licensure are precisely as described in the manual.

1. TYPE OF APPLICATION *(CHECK ONE)*
- ☐ (1) ORIGINAL
- ☐ (2) SUPPLEMENTAL (Check one)
  - ☐ (a) ADDITIONAL LOCATION
  - ☐ (b) REVISED APPLICATION

2. MANUFACTURER'S NAME, ADDRESS AND ZIP CODE

TELEPHONE NO. *(Include Area Code)*

3. ESTABLISHMENT NAME, ADDRESS AND ZIP CODE *(If different than listed in item 2)*

TELEPHONE NO. *(Include Area Code)*

4a. NAME AND ADDRESS OF EACH FACILITY WHERE THERAPEUTIC EXCHANGE PLASMA IS COLLECTED.

4b. SPECIFY WHERE THE COLLECTED PLASMA IS SENT FOR PROCESSING, STORAGE AND DISTRIBUTION.

4c. ARE THE EQUIPMENT AND PERSONNEL TO PERFORM THE EXCHANGE PROCEDURE FURNISHED BY THE MANUFACTURER LISTED IN ITEM 2.
☐ YES ☐ NO

5. INDICATE THE DISEASE STATES OF THE DONORS AND THE INTENDED USES FOR WHICH THE PLASMA IS INTENDED TO BE SOLD FOR FURTHER MANUFACTURING INTO A SPECIFIC DIAGNOSTIC REAGENT.

6a. INDICATE THE TYPE OF EXCHANGE PROCEDURE USED TO COLLECT THE PLASMA.
☐ AUTOMATED ☐ MANUAL

6b. IF AUTOMATED, LIST NAME OF MANUFACTURER MODEL NUMBER OF EQUIPMENT.

7a. IS THE THERAPEUTIC EXCHANGE PLASMA PROCEDURE PRESCRIBED BY LICENSED PHYSICIAN?
☐ YES ☐ NO

7b. IS THE PROCEDURE PERFORMED UNDER THE SUPERVISION OF A LICENSED PHYSICIAN?
☐ YES ☐ NO

7c. IF NO, (ITEM 7b) LIST THE NAMES AND QUALIFICATIONS OF THE INDIVIDUAL RESPONSIBLE FOR PERFORMING THE PROCEDURE.

8. DESCRIBE THE PHYSICAL SETTING FOR PERFORMING THE THERAPEUTIC EXCHANGE PLASMA PROCEDURE *(attach floor plan or layout of the area).* INDICATE ANY PRECAUTIONS TAKEN IF PROCEDURE IS PERFORMED IN SAME ARE USED FOR THE ROUTINE COLLECTION OF BLOOD AND/OR PLASMA.

9a. STATE THE METHOD AND FREQUENCY OF TESTING FOR HEPATITIS *(IF HB $_S$Ag testing is performed at an off-site laboratory, list the name and address of the laboratory.).*

9b. WILL THE PROCEDURE BE PERFORMED ON HB Ag_S POSITIVE INDIVIDUALS? IF SO, STATE THE PRECAUTIONS THAT WILL BE EMPLOYED TO PROTECT STAFF AND OTHER DONORS.

10a. WILL THE PLASMA COLLECTED BY THERAPEUTIC EXCHANGE BE SHIPPED DIRECTLY TO THE DIAGNOSTIC REAGENT MANUFACTURER?

☐ YES ☐ NO

10b. IF NO, DESCRIBE THE METHOD OF DISPOSITION OF THE PLASMA INCLUDING PROCEDURES FOR ASSURING THE FINAL DISPOSITION IS FOR FURTHER MANUFACTURING OF A SPECIAL DIAGNOSTIC REAGENT.

ATTACHMENTS

1. Samples of complete labeling. Labels should be submitted with Form FDA 2567, "Transmittal of Labels and Circulars," in triplicate and may be mock-ups or printer's proofs.

2. Patient/donor Informed Consent form for Therapeutic Exchange Plasma collection. *(Should provide information to the patient/donor that the plasma being collected may be sold for further manufacturing.)*

3. Floor plan or layout of the area(s) used for the collection, testing and storage of the plasma prior to disposition.

4. Standard Operating Procedures Manual for Therapeutic Exchange Plasma Collection. The Manual should include the following information:

   a. Criteria for patient/donor selection, including diagnosis and appropriate specifications *(Such as the nature and titer antibody)* as defined by the manufacturer of the special diagnostic reagent;

   b. Appropriate procedures for the quarantine of the plasma collected at the time of therapeutic exchange until the hepatitis test results have been obtained, plasma has been evaluated for antibody content and disposed of either by shipment or destruction;

   c. A record-keeping system which shows the disposition of all plasma collected by therapeutic exchange by your establishment, and the detailed manufacturing history of the plasma which is intended to be sold for further manufacturing use. The manufacturing history should include such information as the date of collection, diagnosis, volume of Plasma removed, the lot number and manufacturer of software and replacement fluids used, the test procedure and results of tests for HB_SAg and antibody titer; records should be directly cross-referenced to the unit(s) of plasma collected from the patient/donor and should include documentation of any adverse reactions that occur and the treatment of such reactions;

   d. Instructions for labeling, storing and shipping the product.

CERTIFICATION

I certify that there is documentation in the records which supports that, for each unit of THERAPEUTIC EXCHANGE PLASMA prepared, all critical manufacturing steps have been performed in accordance with current Federal Regulations and my Standard Operating Procedure Manual, and that the responsible individual has signed the pertinent manufacturing records on the day of manufacture.

I also certify that all statements made in this application are true and complete to the best if my knowledge and ability. I am familiar with the pertinent Sections of Part 600-640 of Title 21, Code of Federal Regulations, and am aware of my responsibilities described therein.

WARNING: A willfully false certification is a criminal offense. U.S. Code, Title 18, Section 1001.

REMARKS

TYPED NAME OF RESPONSIBLE HEAD	SIGNATURE	DATE